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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/554,683</b>	Applicant(s) <b>Jacobs et al</b>
	Examiner <b>Portner</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on Jan 21, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 1-7, 9, 10, and 12-14 is/are pending in the application.

4a) Of the above, claim(s) 4-7, 10, and 12-14 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-3 and 9 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-7, 9, 10, and 12-14 are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-7, 9-10, 12-14 are pending.

Claims 4-7, 10, 12-14 are withdrawn.

Claims 1-3 and 9 are under consideration.

**Please Note:** The examiner found differences between the “clean copy” and “marked up” copy of the claim amendments submitted. The “clean copy” is being considered to be the Official copy of the claims under examination.

### *Election/Restriction*

1. Applicant continues to traverse the election/restriction requirement made Final in the last Office Action. Arguments were set forth requesting rejoinder of methods of making and using a **novel** product. It is the position of the examiner that the instantly claimed invention has not been indicated to define over the prior art of record and therefore is not considered to be novel. Upon indication of allowable subject matter, Applicant may request rejoinder of a method of making and using the allowed product of the same or equivalent scope as the allowed product, as long as the method of using does not raise any issues under 35 U.S.C. 112.

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***Rejections Withdrawn***

2. Claims 1-3 rejected under 35 U.S.C. 112, second paragraph for the recitation of the phrase "characterized in that", in light of the amendment of the claims.
3. Claim 9 under 35 U.S.C. 112, second paragraph for depending from claim withdrawn from consideration, in light of the claim having been amended to be an independent claim.
4. Claim 9 rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (February 1993) in light of *Campylobacter jejuni* not producing a surface array protein.

***Rejections Maintained***

5. Claim 3 rejected under 35 U.S.C. 112, second paragraph which recites the term "R2", for reasons of record in paper number 6.
6. Claims 1-2 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (1986), for reasons of record in paper number 6, paragraph 10.
7. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Dolby et al (1986), for reasons of record in paper number 6, paragraph 11.

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8. Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994) for reasons of record in paper number 6, paragraph 12.

9. Claim 9 rejected under 35 U.S.C. 102(b) as being anticipated by Kervella et al (August 1993), for reasons of record in paper number 6, paragraph 14.

***Response to Arguments***

10. Applicant's arguments filed January 21, 2002 have been fully considered but they are not persuasive.

11. Applicant responded to the rejection of claim 3 under 35 U.S.C. 112, second paragraph which recites the term "R2", by providing the examiner with the location in the instant specification where R2 is identified on page 3, lines 23-29.

12. While the examiner appreciates the direction to the place in the specification for which the claim evidences support, what characteristics this strain has that other flagellaless strains do not have, was not evident from the narrative found at page 3, lines 23-29. The meaning of this term is not distinctly claimed, because how this strain further limits the composition of antibodies produced, relative to any other flagellaless strains (claim 2 from which claim 3 depends) was not clear from the narrative at page 3, lines 23-29 of the specification. While the claim recites a strain name, R2, how this strain would produce a different composition of antibodies is not distinctly claimed or described in the instant specification.

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13. The rejection of claims 1-2 and 9 under 35 U.S.C. 102(b) as being anticipated by Blaser et al (1986) is asserted to have been obviated through amendment of the claims to recite "effective amount".

14. It is the position of the examiner that the effective amount is any amount that is effective to immunoreact with a flagellaless *Campylobacter* strain. The amount of antibodies to be effective against a single pathogenic cell would differ from the amount that is effective against a disease causing number of *Campylobacter jejuni* bacteria for a chicken or human.

Blaser et al does disclose an antisera obtained (see page 50, line 1) through immunization with the flagellaless strain of *Campylobacter jejuni*. By all comparable data, the antiserum comprised the now claimed antibodies.

No side by side comparison between Applicant's composition of antibodies and the composition of antibodies of Blaser et al showing novel and unobvious differences between the composition of antibodies of the prior art and the instantly claimed invention. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. The rejection is maintained for reasons of record.

15. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Dolby et al.(1986) as only disclosing vaccine compositions comprising whole cell and outer membrane extracts and the vaccines of the instant invention comprise an antiserum to a flagellaless strain of *Campylobacter jejuni*.

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16. It is the position of the examiner that Dolby discloses an antiserum that comprised antibodies that were effective in passively immunizing a young animal which resulted in protection against challenge with a homologous strain of *Campylobacter* ( see abstract, and page 146, SF-2, Table 2; page 144, vaccines section, strain SF-2,(aflagellate)). The antiserum was isolated from the immunized animal. It is this composition that would comprise antibodies with the functional ability to effectively immunoreact with *Campylobacter jejuni* (page 145, paragraph 4) and is considered to comprise vaccine antibodies raised to a flagellaless *Campylobacter jejuni* strain.

No side by side comparison between Applicant's composition of antibodies and the composition of antibodies disclosed by Dolby, showing novel and unobvious differences between the composition of antibodies of the prior art and the instantly claimed invention. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. The rejection is maintained for reasons of record.

17. The rejection of claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994) is argued that Cawthraw does not disclose, teach or suggest a vaccine that comprises an effective amount of antiserum raised against a flagellaless *Campylobacter* strain.

18. It is the position of the examiner that Cawthraw et al disclose anti-*C.jejuni* IgG antibodies induced to a strain of *Campylobacter jejuni* referred to as R2, a flagellaless strain of *Campylobacter jejuni*, wherein the antibodies were administered to eggs and ultimately to young chickens (see page 344, col. 2, second paragraph). The antiserum containing antibodies was

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passively administered to young chicks, wherein antibodies were found in uninfected 1 week old birds, which indicates passive protection afforded to the chick by the antibodies (see page 347, col. 1, last paragraph). The isolated composition of antiserum containing antibodies induced to *C.jejuni* R2 functioned as an effective vaccine to protect the next generation of chicks (Figure 2, page 345). The purified antibodies raised to *C.jejuni* R2 represents a composition of antibodies that was shown to function as a vaccine.

No side by side comparison between Applicant's composition of antibodies to R2 and the composition of antibodies disclosed by Cawthraw was made of record showing novel and unobvious differences between the composition of antibodies of the prior and the instantly claimed invention. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. The rejection is maintained for reasons of record.

19. The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Kervella et al (August 1993) is argued by asserting the Examiner has not set forth any extrinsic evidence that would show that the Kervelle article anticipates Applicant's invention, and points to the antigen and antibodies of Blaser that were protective from a *C.fetus* strain.

20. It is the position of the examiner that the antibodies of Kervella were raised to a 92 kDa antigen of *Campylobacter jejuni* (claimed invention 97 kDa +/- 5kDa), and it is not a *Campylobacter fetus* antigen taught by Blaser. Kervella et al disclose a composition of antibodies to a *Campylobacter jejuni* outer membrane antigen, see page 3447, col. 2, last three lines.

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No side by side comparison between Applicant's composition and the composition of antibodies disclosed by Kervella was made of record showing novel and unobvious differences between the composition of antibodies of the prior and the instantly claimed invention.

Antibodies directed to and protective against *Campylobacter jejuni* antigen of about 97 kDa +/- 5kDa (95 kDa) was known in 1993. Torres et al (1993) is being made of record to show antibodies directed to a *Campylobacter jejuni* surface antigen of about 95 kDa were shown to be effective in providing a host with protection against infection.

No side by side comparison between Applicant's composition of antibodies and the composition of antibodies of Kervella showing novel and unobvious differences between the composition of antibodies of the prior art and the instantly claimed invention. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald et al.*, 205 USPQ 594 and *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999).

### ***Conclusion***

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
22. Glenn-Calvo et al (1994) is cited to show *Campylobacter jejuni* flagellar hook protein of 92 kDa and antibodies thereto.

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23. Cruz,O et al (1993) is cited to show IgA antibodies that immunoreacted with a *Campylobacter jejuni* antigen of 95 kDa, wherein the antibodies provided protection against *Campylobacter* diarrhea.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196

VGP  
April 5, 2002

*LTS*  
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